Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Spikevax 0.2 mg/mL

Dispersion for injection
Active ingredient and its quantity:
elasomeran 1.26 mg/vial
mRNA Vaccine encoding the SARS-CoV-2 spike protein

Inactive ingredients and allergens - see section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine.

- If you have any further questions, consult your doctor or pharmacist.
- This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is the medicine intended for?

Spikevax is an active vaccine used to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

The active substance in Spikevax is mRNA encoding the SARS-CoV-2 spike protein.
The mRNA is embedded in SM-102 lipid nanoparticles.

As Spikevax does not contain the virus, it cannot give you COVID-19.

Therapeutic group: Vaccine, other viral vaccines.

How the vaccine works

Spikevax stimulates the body's natural defences (immune system).
The vaccine works by causing the body to produce protection (antibodies) against the virus that causes COVID-19. Spikevax uses a substance called messenger ribonucleic acid (mRNA) to carry instructions that cells in the body can use to make the spike protein that is also on the virus. The cells then make antibodies against the spike protein to help fight off the virus. This will help to protect you against COVID-19.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6 "Additional information").

Special warnings about using this medicine

Before receiving the vaccine, tell your doctor, pharmacist or the nurse if:

- you have previously had a severe, life-threatening **allergic** reaction after any other vaccine injection or after you were given Spikevax in the past.
- you have a very weak or compromised immune system.

- you have ever fainted following any needle injection.
- you have a bleeding disorder.
- you have a high fever or severe infection; however, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have any serious illness.
- you have anxiety related to injections.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (Inflammation of the lining outside the heart) after vaccination with Spikevax (see section 4).

These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often in younger males, and more often after the second dose compared to the first dose.

Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen.

Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Spikevax.

Capillary leak syndrome (CLS) flare-ups

A few cases of capillary leak syndrome flare-ups (causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint, low blood pressure) have been reported following vaccination with Spikevax. If you have previously had episodes of CLS, talk to a doctor before you are given Spikevax.

Duration of protection

As with any vaccine, the primary 2-dose vaccination course of Spikevax may not fully protect all those who receive it, and it is not known how long you will be protected.

Children and adolescents

This medicine is not indicated for children and adolescents aged under 18 years.

Drug interactions

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including non-prescription medications and nutritional supplements.

Spikevax may affect the way other medicines work, and other medicines may affect how Spikevax works.

Immunocompromised individuals

If you are immunocompromised, you may receive a third dose of Spikevax. The efficacy of Spikevax even after a third dose may be lower in people who are immunocompromised. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Pregnancy, breastfeeding, and fertility

If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

Spikevax can be used during pregnancy. A large amount of information from pregnant women vaccinated with Spikevax during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen.

Spikevax can be given during breastfeeding.

Driving and using machines

Do not drive or use machines if you are feeling unwell after vaccination. Wait until any effects of the vaccine have worn off before you drive or use machines.

Important information about some of the ingredients in this medicine

Spikevax and sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The dose and the method of administration of the vaccine will be determined only by the doctor.

Table 1. Spikevax dosing for primary series, a third dose in severely immunocompromised and booster doses

Strength	Vaccination type	Age(s)	Dose	Recommendations
Spikevax 0.2 mg/mL dispersion for injection	Primary series	Individuals 18 years of age and older	2 (two) doses (0.5 mL each, containing 100 micrograms mRNA)	It is recommended to administer the second dose of the same vaccine 28 days after the first dose.
	Third dose in severely immuno-compromised	Individuals 18 years of age and older	1 (one) dose of 0.5 mL, containing 100 micrograms mRNA	A third dose may be given at least 28 days after the second dose.

	Booster dose	Individuals 18 years of age and older	1 (one) dose of 0.25 mL, containing 50 micrograms mRNA	Spikevax may be used to boost individuals 18 years of age and older who have received a primary series with Spikevax at least 6 months after completion of the primary series.

If you miss an appointment for your primary 2nd dose of Spikevax

- If you miss an appointment, arrange another visit as soon as possible with your doctor, pharmacist, or nurse.
- If you miss a scheduled injection, you may not be fully protected against COVID-19.

Your doctor, pharmacist or nurse will inject the vaccine into a muscle (intramuscular injection) in your upper arm.

After each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for at least **15 minutes** to monitor for signs of an allergic reaction.

Do not exceed the recommended dose.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4. Side effects

Like with all medicines, this vaccine may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Get **urgent** medical attention if you get any of the following signs and symptoms of an allergic reaction:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- hives or rash
- nausea or vomiting
- stomach pain

Talk to your doctor or nurse if you develop any other side effects. These can include:

Very common side effects (may affect more than 1 in 10 people):

- swelling/tenderness in the underarm
- headache
- nausea
- vomiting
- muscle ache, joint aches, and stiffness

- pain or swelling at the injection site
- redness at the injection site (some of which may occur approximately 9 to 11 days after the injection)
- feeling very tired
- chills
- fever

Common side effects (may affect up to 1 in 10 people):
- diarrhoea
- rash
- rash or hives at the injection site (some of which may occur approximately 9 to 11 days after the injection)

Uncommon side effects (may affect up to 1 in 100 people):
- itchiness at the injection site
- dizziness
- stomach pain
- raised, itchy rash (urticaria) (which may occur from the time of injection and up to approximately two weeks after the injection)

Rare side effects (may affect up to 1 in 1,000 people):
- temporary one-sided facial drooping (Bell's palsy)
- swelling of the face (swelling of the face may occur in individuals who have had facial cosmetic injections)
- decreased sense of touch or sensation
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)

Very rare side effects (may affect up to 1 in 10,000 people):
- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Side effects of not known frequency
- severe allergic reactions with breathing difficulties (anaphylaxis)
- reaction of increased sensitivity or intolerance by the immune system (hypersensitivity)
- a skin reaction that causes red spots or patches on the skin that may look like a target or "bulls-eye" with a dark red center surrounded by paler red rings (erythema multiforme)
- extensive swelling of the vaccinated limb
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)
- rash elicited by external stimulus such as firm stroking, scratching, or pressure to the skin (mechanical urticaria)

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects, or by the following link:
https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instructions from the doctor.
- Do not use this vaccine after the expiry date (exp. date) which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Storage conditions:

Unopened vial
- Store frozen between -25°C to -15°C.
- Keep the vial in the outer carton in order to protect from light.
- Do not store on dry ice or below -50ºC.
- The unopened vaccine vial may be stored refrigerated at 2°C to 8°C, protected from light, for a maximum of 30 days. Within this period, up to 12 hours may be used for transportation at 2°C to 8°C.
- Once thawed the vaccine should not be re-frozen.
- The unopened vaccine may be stored at 8°C to 25°C up to 24 hours after removal from refrigerated conditions.

Punctured vial
- Chemical and physical in-use stability has been demonstrated for 19 hours at 2°C to 25ºC after initial puncture (within the allowed use period of 30 days at 2°C to 8ºC and 24 hours at 8°C to 25ºC). From a microbiological point of view, the product should be used immediately. If the vaccine is not used immediately, in-use storage times and conditions are the responsibility of the user.

6. Additional information

What Spikevax contains

Table 2. Composition

Strength	Container	Dose(s)	Composition
Spikevax 0.2 mg/mL dispersion for injection	Multidose vial	Maximum 10 doses of 0.5 mL each	One dose (0.5 mL) contains 100 micrograms of elasomeran, a COVID-19 mRNA Vaccine (nucleoside modified) (embedded in SM-102 lipid nanoparticles).

Strength	Container	Dose(s)	Composition
		Maximum 20 doses of 0.25 mL each	One dose (0.25 mL) contains 50 micrograms of elasomeran, a COVID-19 mRNA Vaccine (nucleoside modified) (embedded in SM-102 lipid nanoparticles).

In addition to the active ingredient, this medicine also contains:
sucrose, SM-102, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), PEG2000 DMG (1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000), tromethamol hydrochloride (Tris-HCl), tromethamol (Tris), sodium acetate trihydrate, acetic acid (Glacial), water for injections.

What the medicine looks like and contents of the pack:

Spikevax is a white to off white dispersion supplied in a 5 mL glass vial with a rubber stopper and red flip-off plastic cap with aluminium seal.

Pack size: 10 multidose vials

Registration holder's name and address:
Medison Pharma Ltd., 10 Hashiloach St., Petach Tikva.

Manufacturer's name and address:
MODERNA BIOTECH SPAIN, S.L.
Calle del Príncipe de Vergara 132 Plt 12
Madrid 28002
Spain

This leaflet was revised in October 2023 according to MOHs guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
168-86-36765

Spikevax-PIL-1023-V1